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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,306	10/17/2000	Ian Reginald Reid	11752-002001	7673

7590 08/13/2003

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[REDACTED] EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
1653	13

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,306	REID ET AL.	
	Examiner Samuel W Liu	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, 34-37 and 41, drawn to a method of stimulating cartilage growth via stimulating chondrocytes proliferation in a patient comprising administering amylin peptide to the patient, are classified in class 514, subclass 2, class 530, subclass 300, and class 424, subclass 93.7.
- II. Claims 19-22, 34, 38-40 and 42, drawn to a method of stimulating cartilage growth via stimulating chondrocytes proliferation in a patient comprising administering adrenomedullin peptide to the patient, are classified in class 514, subclass 2, class 530, subclass 300, and class 424, subclass 93.7.
- III. Claims 23-30, 43, 45-48 and 50, drawn to a method of stimulating cartilage growth in a patient comprising activating a receptor via administering to the patient amylin agonist, are classified in class 514, subclass 2, class 424, subclass 93.7, and class 435, subclass 7.1
- IV. Claims 23-27, 31-33, 43-47, 49 and 51 drawn to a method of stimulating cartilage growth in a patient comprising activating a receptor via administering to the patient adrenomedullin agonist, are classified in class 514, subclass 2, class 424, subclass 93.7, and class 435, subclass 7.1.

The inventions are distinct, each from the other for the following reasons:

Inventions I - IV are directed to different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Inventions I, II, III and IV since they constitute patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome.

Inventions I and II are directed to the different polypeptides; amylin of Invention I differs from adrenomedullin of Invention II in their structures (amylin consists of 37 amino acid

residues while adrenomedullin 52 residues; moreover, there is only less than 20% sequence identity between these two polypeptides).

Inventions I and II are distinct from Inventions III and IV in that ingredients which the inventions employ, amylin and adrenomedullin, are structurally distinct molecules, and the modes of action and the method step(s) of the Inventions are different. Inventions I and II are directed to the method comprising the step of increasing active concentration of the polypeptide (amylin or adrenomedullin) by administering amylin or adrenomedullin polypeptide whereas Inventions III and IV are directed to the method comprising the step of activating a receptor. Note that the action of a receptors are distinct from the mechanisms of the polypeptides *per se*, because the receptor involves agonists/antagonist which may be or may not be the amylin or adrenomedullin and that there are at least two independent amylin receptors (see Christopoulos, G. et al. (1999) *Mol. Pharmacol.* 56, 235-242, page 236, the left column, the second paragraph), and because receptor as much broader action spectrum than a polypeptide that acts as agonist or antagonist to the receptor.

Further, Invention III differs from Invention IV in that receptor(s) for amylin (Invention III) structurally and functionally differs from the receptor(s) for adrenomedullin (Invention IV) as amylin and adrenomedullin bind to different receptors (see Table 1 and Figure 1 of Fischer J. A. et al. reference: *Biochem. Soc. Trans.* (2002) 30, 455-459), even amylin can bind to the distinct receptors (see the above statement regarding Christopoulos, G. et al. reference).

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general

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nature or relating to the status of this application should be directed to the Technology Center
1600 receptionist whose telephone number is (703) 308-0196.

Swl

Samuel W. Liu, Ph.D.

August 7, 2003

Karen Cochrane Carlson R.D.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER